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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 09/910,887 | 07/24/2001 | Dong Huang | P444 0001 | 3331 |
| 23307 | 7590 | 09/09/2004 | EXAMINER | |
| SYNNESTVEDT & LECHNER, LLP 2600 ARAMARK TOWER 1101 MARKET STREET PHILADELPHIA, PA 191072950 | | | | QAZI, SABIHA NAIM |
| ART UNIT | | PAPER NUMBER | | |
| | | | | 1616 |

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/910,887 | HUANG ET AL. |
| | Examiner | Art Unit |
| | Sabiha Qazi | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 10 is/are allowed.
- 6) Claim(s) 9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Final Office Action

Acknowledgment is made of the remarks filed on May 17, 2004. Amendments are entered.

Claims 9 and 10 are pending. Claim 10 is allowed.

Declaration filed on Don Huang has been fully considered. The arguments are found persuasive, in part. The difference between the prior art compound Rh5 and presently claimed compound PAM-120 (compound of claim 9) is the substitution at 3 position. In presently claimed compound PAM-120, hydroxy group is present at 3 position, whereas in the prior art compound Rh5, hydroxy group is substituted by O-Glc group. The side-by-side comparison should be the comparison between PAM-120 and Rh5. Applicants' argument that Rh5 and Rh3 being identical as cited on the first paragraph of Page 12 of the Remarks filed on 5/17/04 is not found persuasive. It is not appropriate to consider the results of one experiment in one condition with another experiment in another condition. Applicants are requested to do a side-by-side comparison of Rh5 and PAM-120.

All rejections, except the rejection under USC 103, are withdrawn as claims are canceled.

Claim Rejections - 35 USC § 103

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al., Yun et al. and Sung Won Kwon et al. See the entire documents. All the references cited above teach dammarane sapogenins and saponins, which embraces Applicant's claimed invention.

1. Determining the scope and contents of the prior art.

Park et al. teach ginseng saponins for multidrug resistance, see the entire document and structure of compounds cited above. Sang-Kwon et al teaches the ginsenoside Rg3 inhibition on multi drug resistance, see the entire document especially page 336 where anticancer activity of the gingenosides are disclosed; Yun et al. teaches anticarcinogenic effect and identification of active compound, Ginsenoside Rg3, Rg5 and Rh2 were found to be active anticarcinogenic compounds and they are said to prevent cancer either singularly or synergistically, see the abstract, Tables 1-8, fig. 1-3 and compounds on page S 13; Park teach ginseng saponin compounds and their use as antitumor agent. Similar sapogenins and saponins as positional isomer (double bond at different position in the side chain attached at 17-position) is instantly claimed. See compound at page S13, Rg5 in Yun et al. which has the following structure.

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims drawn to compounds and method of use differs from the references in claiming a different position of double bond in the side chain at 17-position. Even though by disclaiming certain compounds for anticipation, instant invention is considered obvious over the prior art, because instant invention is the positional isomer of the prior art.

3. Resolving the level of ordinary skill in the pertinent art.

Since presently claimed compounds are the positional isomer of the prior art, or saponins are known one having ordinary skilled in the art in search for additional dammarane sapogenins or saponins would be motivated to isolate or prepare such compounds and would expect anticancer activity. Cleavage of sugar from saponins to get sapogenins is conventional and is known to one skilled in the art. This would not be a patentable distinct matter.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Since instant sapogenins and saponins are isolated from ginseng as in instant invention and posses anticancer and multi resistance properties which is considered obvious to one skilled in the art at the time of invention to prepare isomers and expecting the same properties which is taught by the prior art for similar compounds. In absence of showing any criticality or unexpected results presently claimed invention is considered obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Friday, September 3, 2004